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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/020,393

02/09/1998

PETER J. SIMS

OMRF-170

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32425

7590

09/23/2005

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EXAMINER

GAMBEL, PHILLIP

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/020,393

Applicant(s)

SIMS, PETER J.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3/26/03; 7/23/3.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9-11, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 4, 8, 12-15, 18-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Applicant's amendment, filed 7/23/03, is acknowledged.

Applicant's amendment, filed 1/21/04, has been entered.

Claims 1-15 and 18-19 have been amended

Claims 20-35 have been canceled.

Claims 1-19 are pending.

2. The Decision On Appeal, mailed 3/26/03, is acknowledged.

It is noted that the Decision raised the issue of double patenting raised by appellant 's bringing attention to U.S. Patent No. 5,843,884, issued 12/1/98.

3. Applicant's Status Inquiry, filed 3/21/05, is acknowledged.

The examiner apologizes for any inconvenience to applicant in this matter.

### Obvious Double Patenting

4. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3, 5, 6 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,843,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are drawn to peptides, anti-idiotypic antibodies and cyclized peptides which bind to the same C9 amino acid specificity as claimed in the instant application and thereby anticipate the instant claims.

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6. Applicant's amendment, filed 1/21/04, discussing the distinctions between the claims of U.S. Patent No. 5,843,884 and the instant claims have been fully considered but have not been found convincing.

Applicant asserts that the U.S. Patent No. 5,843,884 is drawn to compounds binding the species-specific region of C9, unlike this case which is drawn to compounds mimicking the species-specific region of CD59 and that the patented claims corresponds to the Chang reference cited in the prosecution history of the instant application.

However, the instant claims recite limitations drawn to peptides, including cyclized peptides, and anti-idiotypic antibodies that appear to have the same or nearly the same structure and function of the human CD59 amino acid residues 42-58 of SEQ ID NO: 3 and which bind the same or nearly the same human C9 amino acids residues as the "molecules" claimed in U.S. Patent No. 5,843,884.

Further, the instant claims no longer recite "structurally mimicking", as asserted by applicant.

Applicant is invited to distinguish the differences between the instant claims and the patented claims.

In contrast to applicant's assertions, it appears that the instant claims and the patented claims as currently recited would either anticipate or render obvious each other.

#### **35 USC § 112 first paragraph**

7. Given applicant's amended claims, filed 7/23/03, the following rejection under 35 U.S.C. 112, first paragraph, written description has been set forth.

Claims 1-2, 7, 10-11 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims encompass "peptidomimetics having the structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3", including "a nucleic acid" and "a small molecule", however there is insufficient written description of such "nucleic acids" and "small molecules" having the structure and function of the claimed "peptidomimetics" in the application as filed.

The instant specification and claims do not provide functional characteristics coupled with a known or disclosed correlation between function and structure as it reads on "nucleic acids" and "small molecules" as "peptidomimetics having the structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3".

For example, page 11 of the instant specification describes "peptidomimetics" that present the surface exposed side chain in amino acids in the same relative positions as those positions of CD59 which bind to active portions of human C9.

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While the specification discloses a starting point for screening or testing for compounds that bind a given ligand that are identified by combinatorial chemistry (e.g. see pages 17-18 of the instant specification), the instant disclosure does not set forth sufficient procedures that will necessarily lead to discovery for such a compound and it does not identify suitable members of compounds such as a nucleic acid that has the structure and function of CD59 to provide a sufficient number of species to support the claimed genus of "nucleic acid nor small molecule peptidomimetics".

The application does no more than describe the desired function of the claimed nucleic acid and small molecule peptidomimetics broadly encompassed by the claimed invention and does not contain sufficient information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention.

The claimed methods depend upon finding "a nucleic acid or a small molecule peptidomimetic that has the structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3", yet the basic structure and mode of action of nucleic acids and small molecules differ from polypeptides and antibodies.

Applicant has provided insufficient disclosure of the identifying structural characteristics or information that would contribute to the appropriate conformation to transition from protein-based or antibody-based peptidomimetics to nucleic acid or small molecule peptidomimetics having the structure and function of human CD59. No structure-function / activity and conformational studies with nucleic acid or small molecule peptidomimetics have been provided.

Without such a compound, the skilled artisan cannot practice the claimed products and method. It means little to invent a method if one does not have possession of the compound(s) that is (are) essential to practice the method. Without possession of the compound(s), the claimed products and therapeutic endpoints are illusory and there is no meaningful possession of the claimed invention, as it is drawn to "nucleic acid and small molecule peptidomimetics".

Applicant has not provided sufficient written description of a "nucleic acid or small molecule having the claimed structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

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In the absence of working examples or functional characteristics that are shared by members of the genus of "nucleic acid or small molecule peptidomimetics" having "the structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3", one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606).

Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

There is insufficient written description of the claimed structural and functional characteristics that are shared by members of the genus of "nucleic acid or small molecule peptidomimetics" having "the structure and function of human CD59 amino acid residues 42-58 of SEQ ID NO: 3" broadly encompassed by the claimed invention. There is a lack of disclosure of sufficient relevant identifying characteristics coupled with a known or disclosed correlation between function and structure of the broadly claimed "nucleic acid and small molecule peptidomimetics" encompassed by the claims.

Also see the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Also, see MPEP 2163.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

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**35 USC § 112 second paragraph**

8. Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 lacks proper antecedent basis for the recitation of "in the compound are equivalent to the spatial orientation and alignment deduced by NMR structure determination", as independent claim 1 no longer recites "spatial orientation".

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

**Claim Objection**

9. Claims 1 and 10 are objected to because "anti-ID" should be spelled out as "anti-idiotypic" for clarity.


10. Claims 4, 8, 12-15, 18-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

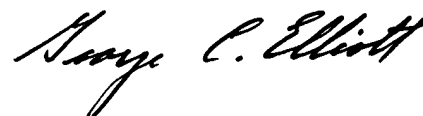
**Conclusion**

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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September 16, 2005

  
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